



Health Canada authorizes AstraZeneca and Verity Pharmaceuticals Inc./Serum Institute of India COVID-19 vaccines

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Statement

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Today, Health Canada authorized two vaccines; the COVID-19 vaccine manufactured by AstraZeneca, and developed in partnership with Oxford University, and, the Serum Institute of India's version of the AstraZeneca vaccine.

Health Canada received an application for authorization from AstraZeneca on October 1, 2020, and from Verity Pharmaceuticals Inc./Serum Institute of India (in partnership with AstraZeneca Canada Inc.) on January 23, 2021. After thorough, independent reviews of the evidence, the Department has determined that these vaccines meet Canada's stringent safety, efficacy and quality requirements.

Health Canada's authorization of the Verity Pharmaceuticals Inc./Serum Institute of India product relies on the assessment of its comparability to the AstraZeneca-produced version of the vaccine.

These are the first viral vector-based COVID-19 vaccines authorized in Canada. The vaccines are authorized for use in people over 18 years of age. They are administered as a two-dose regimen and can be kept at refrigerated temperatures (from 2 °C to 8 °C) for at least six months, facilitating distribution across the country.

These vaccines were authorized with terms and conditions under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. This process allowed Health Canada to assess information submitted by the manufacturer as it became available during the product development process, while maintaining Canada's high standards.

Health Canada has placed terms and conditions on the authorizations requiring the manufacturers to continue providing information to Health Canada on the safety, efficacy and quality of the vaccines to ensure their benefits continue to be demonstrated through market use.

In keeping with the Department's commitment to openness and transparency, Health Canada is publishing a number of documents related to its decisions, including high-level summaries of the evidence it reviewed to support the authorizations of the vaccines. More detailed information will be available in the coming weeks, including detailed scientific summaries and the full clinical trial results that support the use of the vaccines.

Health Canada and the Public Health Agency of Canada will closely monitor the safety of these vaccines once they are on the market and will not hesitate to take action if any safety concerns are identified.

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